Aims

Journal clubs are educational interventions that can improve reading habits, knowledge of clinical epidemiology and biostatistics, and the use of medical literature in clinical practice for postgraduate physicians in training (Medical Teacher, Vol. 23, No. 5, 2001).

During the course of the program, each third-year internal medicine resident (PGY-3) will be responsible for presenting at least three to four Evidence-Based Medicine Journal Club meetings on a topic related to internal medicine or its subspecialties. This experience fulfills several goals of the research curriculum such that at its conclusion each resident will be able to:

1. Conduct structured critical appraisal
2. Understand the limitations of the application of evidence
3. Recognize and understand basic study design, distinguishing weak from strong methodology
4. Gain familiarity with basic statistical tests
5. Gain insight into a specific clinical problem
6. Hone skills related to oral and written presentations

Expectations

Presenting Resident

You will be assigned an article, a date and a preceptor. Except under extraordinary circumstances, these will not be changed. Any problems with either assignment (article, date or preceptor) should be brought to the attention of the Chief Resident or Program Director as early as possible. The primary responsibility for the EBM Journal Club rests with the presenting resident and the faculty preceptor.

Responsibilities

1. You will be assigned a primary article and a faculty preceptor 6 weeks prior to your presentation (see criteria for articles below).
2. Once you have read and reviewed the article, ensure that the article is distributed to the residents and faculty at least 2 weeks prior to the date of your presentation. This can be done electronically via email to the Residents mailing list from your registered address. (PDF's are preferred but hard copies may be placed in the Chief Resident’s office).
3. Pick 1-3 supporting articles to go with the primary article. Supporting articles might include up-to-date reviews, classic articles on the subject or studies that support or refute the results of the primary article.
4. Read the article and decide what type it is (Therapy or Harm, Prognosis, Diagnosis, Symptom prevalence, Economic or Decision Analysis). Most articles will fall into the first three categories. Worksheets are best used to analyze and evaluate the article content (see Resources).
5. Develop your presentation and produce a final critique.
Process

A recent systematic review identified 3 "best practices" for journal clubs: (1) use of a structured checklist, (2) explicit written learning objectives, and (3) a formalized meeting structure and process.

Article Selection

Articles will be selected by the Chief Resident in conjunction with the Program Director and will comprise core internal medicine articles published within the prior 2 years from one of the five frequently cited medicine journals: Annals of Internal Medicine, BMJ, JAMA, The Lancet, and the New England Journal of Medicine. Relevant articles from internal medicine subspecialties may be chosen from the respective literature when the contribution to general medicine practice is beneficial. The articles chosen should provide a level of evidence of grade 1a or 1b (see Appendix)

Review

Typically, review of the article will address the following 8 domains (Annals of Family Medicine 4:196-197 (2006)):

1. Issues addressed by the article—What is the research question? Why does it matter? How does it fit with what already is known? How can it help solve important problems for practice or policy?
2. Design of the study—Is the study design appropriate for the question and what already is known about the question?
3. Study methods—To what degree can the findings be accounted for by:
   - How participants were selected?
   - How key variables were defined and measured?
   - Confounding (false attribution of causality because two variables discovered to be associated actually are associated with a third factor)?
   - How information was interpreted?
   - Chance (as indicated by inferential statistics)?
4. Main findings—Does this study advance current knowledge?
5. Generalizability—How transportable are the findings to other settings, particularly to my patients, practice and community?
6. Implications—How can the information be used to change practice, policy or training?
7. Constituencies—Who are the constituencies for the findings, including patients, and how might they be engaged in interpreting or using the findings?
8. Next steps/new questions—What are the next steps in interpreting or applying the findings? What new questions arise and how might they be best answered?

Presentation

Your presentation will be done in PowerPoint® and should be roughly organized as follows:

- Topic Background (state why this is important) 3 min
- Outline a hypothetical (or real) case (one slide, keep it brief) 2 min
• Present the paper (make use of figures and tables) 10 min
  o Methods
  o Results
• Present your critical appraisal (this is best done with a slide for each of the questions outlined above and your answers for each). 10 min
• Sum up. Derive your conclusion and how these results will affect YOUR practice. 5 min

Aim to complete your presentation within the 30 allotted minutes, as there shall be two articles presented per session and there should be time for a few questions from the attendees. Try not to consume excess time or get too over-involved in one aspect of the article (e.g., application of statistical methods). If this cannot be resolved quickly, it's your duty to indicate this and move on.

Resources

Critical Appraisal Worksheets
Learning Tools for Evidence Based Practice
http://www.ebmtips.net/

Douglas G. Altman, Kenneth F. Schulz, David Moher, Matthias Egger, Frank Davidoff, Diana Elbourne, Peter C. Götzsche, Thomas Lang for the CONSORT Group
The Revised CONSORT Statement for Reporting Randomized Trials: Explanation and Elaboration

The CONSORT statement: revised recommendations for improving the quality of reports of parallel group randomized trials.
BMC Medical Research Methodology 2001, 1:2
The electronic version of this article is the complete one and can be found online at:
http://www.biomedcentral.com/1471-2288/1/2

Being Smarter About Clinical Trials: A Report of the NIH Workshop
Moving From Observational Studies to Clinical Trials: Why Do We Sometimes Get It Wrong?
January 11–12, 2005
http://www.meetinglink.org/omar/ct/agenda.htm#agenda

The Cochrane Handbook for Systematic Reviews of Interventions
http://www.cochrane.org/resources/handbook/

Postgrad. Med. J. 2004;80;140-147
http://pmj.bmjjournals.com/cgi/reprint/80/941/140

How to Read a Paper
Trisha Greenhalgh
BMJ Publishing Group
http://bmj.bmjjournals.com/collections/read.shtml
## Appendix: Levels of Evidence

<table>
<thead>
<tr>
<th>Grade of recommendation</th>
<th>Level of Evidence</th>
<th>Therapy: Whether a treatment is efficacious/effective/harmful</th>
<th>Therapy: Whether a drug is superior to another drug in its same class</th>
<th>Prognosis</th>
<th>Diagnosis</th>
<th>Differential diagnosis/symptom prevalence study</th>
<th>Economic and decision analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1a</td>
<td>SR (with homogeneity*) of RCTs</td>
<td>SR (with homogeneity**) of head-to-head RCTs</td>
<td>SR (with homogeneity*) of inception cohort studies; CDR† validated in different populations</td>
<td>SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres</td>
<td>SR (with homogeneity*) of prospective cohort studies</td>
<td>Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses</td>
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<td></td>
<td>1b</td>
<td>Individual RCT (with narrow Confidence Interval†)</td>
<td>Within a head-to-head RCT with clinically important outcomes</td>
<td>Individual inception cohort study with &gt;80% follow-up; CDR† validated in a single population</td>
<td>Validating** cohort study with good††† reference standards; or CDR† tested within one clinical centre</td>
<td>Prospective cohort study with good follow-up***</td>
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<tr>
<td></td>
<td>1c</td>
<td>All or none§</td>
<td>All or none case-series</td>
<td>All or none case-series</td>
<td>Absolute SpPins and SnNouts††</td>
<td>All or none case-series</td>
<td>Absolute better-value or worse-value analyses†††</td>
</tr>
<tr>
<td>B</td>
<td>2a</td>
<td>SR (with homogeneity*) of cohort studies</td>
<td>Within a head-to-head RCT with validated surrogate outcomes</td>
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<td></td>
<td>2b</td>
<td>Individual cohort study (including low quality RCT; e.g., &lt;80% follow-up)</td>
<td>Across RCTs of different drugs v. placebo in similar or different patients with clinically important or validated surrogate outcomes</td>
<td>Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR† or validated on split-sample§§§ only</td>
<td>Exploratory** cohort study with good††† reference standards; CDR† after derivation, or validated only on split-sample§§§ or databases</td>
<td>Retrospective cohort study, or poor follow-up</td>
<td>Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses</td>
</tr>
<tr>
<td>C</td>
<td>3a</td>
<td>SR (with homogeneity*) of case-control studies</td>
<td>Across subgroup analyses from RCTs of different drugs v. placebo in similar or different patients, with clinically important or validated surrogate outcome</td>
<td>SR (with homogeneity*) of 3b and better studies</td>
<td>SR (with homogeneity*) of 3b and better studies</td>
<td>SR (with homogeneity*) of 3b and better studies</td>
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<td>3b</td>
<td>Individual Case-Control Study</td>
<td>Across RCTs of different drugs v. placebo in similar or different patients but with unvalidated surrogate outcomes</td>
<td>Non-consecutive study; or without consistently applied reference standards</td>
<td>Non-consecutive cohort study, or very limited population</td>
<td>Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.</td>
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<tr>
<td>D</td>
<td>4</td>
<td>Case-series (and poor quality cohort and case-control studies§§ )</td>
<td>Between non-randomised studies (observational studies and administrative database research) with clinically important outcomes</td>
<td>Case-series (and poor quality prognostic studies *** )</td>
<td>Case-control study, poor or non-independent reference standard</td>
<td>Case-series or superseded reference standards</td>
<td>Analysis with no sensitivity analysis</td>
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<tr>
<td></td>
<td>5</td>
<td>Expert opinion without explicit critical appraisal, or based on physiology, bench research or &quot;first principles&quot;</td>
<td>Expert opinion without explicit critical appraisal, or based on physiology, bench research or &quot;first principles&quot;</td>
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<td>Expert opinion without explicit critical appraisal, or based on physiology, bench research or &quot;first principles&quot;</td>
<td>Expert opinion without explicit critical appraisal, or based on economic theory or &quot;first principles&quot;</td>
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</table>
Appendix: Levels of Evidence

1. These levels were generated in a series of iterations among members of the NHS R&D Centre for Evidence-Based Medicine (Bob Phillips, Chris Ball, Dave Sackett, Brian Haynes, Sharon Straus and Finlay McAlister).

2. Users can add a minus-sign "-" to denote the level of that fails to provide a conclusive answer because of:
   
   EITHER a single result with a wide Confidence Interval (such that, for example, an ARR in an RCT is not statistically significant but whose confidence intervals fail to exclude clinically important benefit or harm)

   OR a Systematic Review with troublesome (and statistically significant) heterogeneity.

3. Grades of recommendation are shown as linked directly to a level of evidence. However levels speak only of the validity of a study not its clinical applicability. Other factors need to be taken into account (such as cost, easy of implementation, importance of the disease) before determining a grade. Grades that are currently in the guides link closely to the validity of the evidence - these will change over time to reflect better concerns that we highlight in the text of the guide or related CATs.

Notes

By homogeneity we mean a systematic review that is free of worrisome variations (heterogeneity) in the directions and degrees of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant. As noted above, studies displaying worrisome heterogeneity should be tagged with a "-" at the end of their designated level.

Clinical Decision Rule. (These are algorithms or scoring systems which lead to a prognostic estimation or a diagnostic category)

See comment #2 for advice on how to understand, rate and use trials or other studies with wide confidence intervals.

Met when all patients died before the Rx became available, but some now survive on it; or when some patients died before the Rx became available, but none now die on it.

By poor quality cohort study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or failed to identify or appropriately control known confounders and/or failed to carry out a sufficiently long and complete follow-up of patients. By poor quality case-control study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls and/or failed to identify or appropriately control known confounders.
Split-sample validation is achieved by collecting all the information in a single tranche, then artificially dividing this into "derivation" and "validation" samples.

An "Absolute SpPin" is a diagnostic finding whose Specificity is so high that a Positive result rules-in the diagnosis. An "Absolute SnNout" is a diagnostic finding whose Sensitivity is so high that a Negative result rules-out the diagnosis.

Better-value treatments are clearly as good but cheaper, or better at the same or reduced cost. Worse-value treatments are as good and more expensive, or worse and equally or more expensive.

Good reference standards are independent of the test, and applied blindly or objectively to applied to all patients. Poor reference standards are haphazardly applied, but still independent of the test. Use of a non-independent reference standard (where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference') implies a level 4 study.

Validating studies test the quality of a specific diagnostic test, based on prior evidence. An exploratory study collects information and trawls the data (e.g. using a regression analysis) to find which factors are 'significant'.

By poor quality prognostic cohort study we mean one in which sampling was biased in favour of patients who already had the target outcome, or the measurement of outcomes was accomplished in <80% of study patients, or outcomes were determined in an unblinded, non-objective way, or there was no correction for confounding factors.

Good follow-up in a differential diagnosis study is >80%, with adequate time for alternative diagnoses to emerge (eg 1-6 months acute, 1 - 5 years chronic)

Surrogate outcomes are considered validated only when the relationship between the surrogate outcome and the clinically important outcomes has been established in long-term RCTs.

References